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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,451	07/31/2001	Louis Schofield	017227/0174	8055

22428 7590 04/17/2003

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/17/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/830,451

Applicant(s)

SCHOFIELD ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/4/02, 7/31/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 78-137 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 and 78-137 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 78-136 on pages 5-12 of the amendment filed 11/4/02 have been renumbered as claims 79-137 according to 37 CFR 1.126 because when claims are added, they must be numbered by the Applicant consecutively beginning with the number next following the highest numbered claim previously presented.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-18 and 79-125, drawn to a method of activating T cells/treatment and/or prophylaxis of a disease/condition comprising administration of GPI, derivative or equivalent thereof or a complex thereof.

II. Claims 78 and 135-137, drawn to a composition comprising GPI, derivative or equivalent thereof or a complex thereof.

III. Claims 126-134, drawn to a method of making a medicament using GPI, derivative or equivalent thereof or a complex thereof.

3. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 78 and 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Sieling et al, 1995 (cited in the International Search Report for PCT/AU99/00929). Sieling et al teach a composition comprising GPI which is presented by CD1 and a method of activating T cells using the said composition.

Therefore, the instant invention lacks Unity of Invention.

Art Unit: 1644

4. **If Applicant elects Group I**, Applicant is further required to elect a (1) specific method of inducing an immune response or treatment or prophylaxis of a specific condition (**a specific mammalian disease condition, or upregulation of a Th1 response or upregulation of a Th2 response**) using (2) a single disclosed species of GPI, derivative, equivalent or complex thereof, (**a specific GPI, derivative or equivalent or complex thereof**, for example, one of the single disclosed species recited in claim 11, and if a complex is used, **a specific complex comprising a specific species of GPI and other component of the said complex**, MSP-1, for example), to which claims would be restricted if no generic claim is finally held to be allowable and (3) to list all claims readable thereon including those subsequently added.

These species are distinct because they are different methods using different agents with different structures.

5. **If Applicant elects Group II**, Applicant is further required to (1) elect a single disclosed species (**a specific GPI, derivative or equivalent or complex thereof**, for example, one of the single disclosed species of GPI, and if a complex is used, **a specific complex comprising a specific species of GPI and other component of the said complex**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

6. **If Applicant elects Group III**, Applicant is further required to elect a specific method of making a specific medicament for treatment/prophylaxis of (1) **a specific disease**, for example, Leishmania, **characterized by the insufficiency of a specific Th response**, for example, a Th1 response, (2) a single disclosed species (**a specific GPI, derivative or equivalent or complex thereof**, for example, one of the single disclosed species of GPI, and if a complex is used, **a specific complex comprising a specific species of GPI and other component of the said complex**) to which claims would be restricted if no generic claim is finally held to be allowable and (3) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

7. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Art Unit: 1644

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

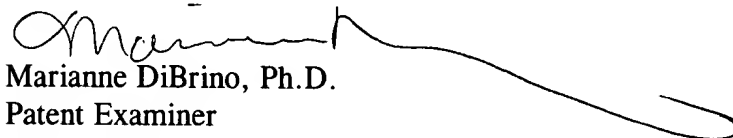
11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday and Thursday from 11 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.




Marianne DiBrino, Ph.D.  
Patent Examiner

Group 1640

Technology Center 1600

April 7, 2003



CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600